REMARKS

Claims 1-18 and 29-38 are pending in the instant application. Claims 1-18 and 29-38 have been rejected. Claims 1, 3, 7, 8, 9, 10, 12, 16, 17, 18, 34 and 35 have been amended. Claims 2, 4-6, 11, 13-15, 29-33, and 36-38 have been canceled without prejudice in light of amendments to claims 1, 3, 7, 8, 9, 10, 12, 16, 17, 18, 34 and 35. Support for these claim amendments is provided throughout the specification and in particular at page 8, lines 21-26, page 15, lines 3-5, pages 26-32 and pages 38-39. New claim 39 has been added. Support for this claim is provided throughout the specification and in particular at page 11, lines 26-28, and page 12, lines 19-21. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 31 and 32 under 35 U.S.C. § 112, second paragraph

Claims 31 and 32 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests

that there is insufficient antecedent basis for the limitation of host cell and donor host cell in line 2 of these claims.

It is respectfully pointed out, however, that claims 31 and 32 have been canceled, without prejudice, thus mooting this rejection. Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 1-18 and 29-38 under 35 U.S.C. § 112, first paragraph

Claims 1-18 and 29-38 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, with respect to recitation of "cellular immunogen", the Examiner suggests that there appears to be an inadequate written description in the specification as-filed of the essential structural feature that provides the recited function of immunization of hosts against products of target proto-oncogenes.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of a cellular immunogen as encompassing "*any* molecule with the functional activity of generating an immune response against said antigen". In

accordance with MPEP § 2163(II)(A)(1), when determining adequacy of written description, claims are to be given their broadest reasonable interpretation in light of and consistent with the written description. Also see *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). As made clear by Applicants in both the specification and the claims, the term "cellular immunogen" is meant to comprise cells which are allogeneic with respect to the host and which have been transfected with at least one vector comprising at least one non-transforming transgene cognate to the target proto-oncogene and a strong promoter to drive the expression of the non-transforming cognate transgene in the transfected cells. The non-transforming cognate transgene of the vector is derived by deletion of a sequence of the transgene essential for transformation, consists of wild-type sequence outside the deleted sequence, and encodes a gene product which induces host immunoreactivity to host self-determinants of the product of the target proto-oncogene gene. Thus, it is this claimed cellular immunogen which Applicants must show possession of, not "*any* molecule with the functional activity of generating an immune response against said antigen" per the Examiner's suggestion.

Further, Applicants respectfully disagree with the

Examiner's suggestion that any and all cellular immunogens expressing target oncogenes must be reduced to practice to meet the written description requirements of 35 U.S.C. § 112, first paragraph.

Instead, what is required to satisfy the written description requirements of 35 U.S.C. §112, first paragraph, is a patent specification which describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See MPEP § 2163(I) and *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. While actual reduction to practice is one means for evidencing possession, possession can also be shown by disclosure of sufficiently detailed, relevant identifying characteristics such as complete or partial structures, other physical or chemical properties, functional characteristics when coupled with a known correlation between function and structure, or some other combination of characteristics. See MPEP § 2163 (3)(a).

Applicants clearly show possession in teachings of the specification of multiple cellular immunogens as claimed. For example, Table 1 at pages 17-26 provides an extensive list of exemplary target proto-oncogenes and their corresponding normal

cellular homologs. Detailed teachings for selection of cognate transgenes and non-transforming cognate transgenes as well as screening for cognate transgenes are provided at pages 26-28, 30-32 and 29-30, respectively, and Table 2 at pages 35-38 provides an extensive list of exemplary non-transforming cognate transgenes for use in the cellular immunogens. References disclosing the structures, physical properties and names for these exemplary proto-oncogenes and cognate transgenes are also provided in Tables 1 and 2. Thus, further disclosure by Applicants in the instant specification of the structure, physical properties, etc. of these known proto-oncogenes and transgenes is not required to meet the written description requirements of 35 U.S.C. § 112, first paragraph. See MPEP § 2163(3)(a) and *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94 and *Fonar Corp. v. General Electric Co.* 107 F.3d at 1549, 41 USPQ2d at 1805. Further, vectors used to transfect allogeneic cells to produce the cellular immunogens of the present invention, allogeneic cells used in the cellular immunogens of the present invention, and methods for transfecting the allogenic cells with these vectors to produce the cellular immunogens of the present invention are described in detail in the specification at pages 38-42 of the instant specification.

Finally, at pages 44-54, two different exemplary cellular immunogens within the scope of the instant claims are demonstrated to induce host immunoreactivity to host self-determinants of the product of the target proto-oncogene gene as claimed.

Thus, the specification clearly provides sufficient detail regarding structural and functional characteristics of the instant claimed invention to place the public in possession of what Applicants have claimed as their invention and to clearly convey the information that Applicants have invented the subject matter which is claimed. Therefore, the instant specification meets both objectives as set forth in MPEP § 2163 (I) of the written description requirement. Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

III. Rejection of Claims under 35 U.S.C. § 102(b)

Claims 1, 2, 8, 9, 10, 11, 17 and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Johnson et al. (Mol. Cell. Biol. 1985 5(5):1073-1083). The Examiner suggests that Johnson et al. teach a fibroblast cell line that is transformed with a c-src proto-oncogene and a method of constructing this transformed cell.

Claims 1, 2, 8, 10, 11, 17 and 29 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by Korngold et al. (transplantation 1994 58(3):278-87). The Examiner suggests that Korngold et al. teach a MMB3.19 cell line that is transformed with a c-myc proto-oncogene which is used as a cellular immunogen and a method for preparing the cellular immunogen.

Applicants respectfully traverse these rejections.

At the outset, it is respectfully pointed out that the claims have been amended to clarify that the cellular immunogen comprises cells which are allogeneic with respect to the host and which have been transfected with at least one vector comprising at least one non-transforming transgene cognate to the target proto-oncogene. As made clear in the claims as amended, the non-transforming cognate transgene is derived by deletion of a sequence of the transgene essential for transformation and consists of wild-type sequence outside the deleted sequence. The non-transforming cognate transgene encodes a gene product which induces host immunoreactivity to host self-determinants of the product of the target proto-oncogene gene. Support for these claim amendments can be found throughout the specification and in particular at pages 30-32, Table 2 at pages 35-38, and page 38.

Neither Johnson et al. nor Korngold et al. teach allogeneic

cells transfected with a vector comprising a non-transforming cognate transgene derived by deletion of a sequence of the transgene essential for transformation and consisting of wild-type sequence outside the deleted sequence.

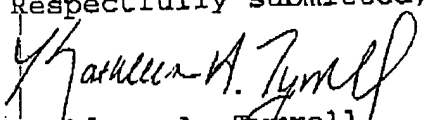
Thus, since these references do not teach all the elements of the invention as claimed, these references cannot anticipate the claimed invention. See MPEP § 2131.

Withdrawal of these rejections under 35 U.S.C. § 102(b) is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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